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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/723,043

11/26/2003

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50623.309

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7590

06/03/2009

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

06/03/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/723,043 | <b>Applicant(s)</b><br>PACETTI, STEPHEN D. |  |
|                              | <b>Examiner</b><br>ERIC E. SILVERMAN | <b>Art Unit</b><br>1618                    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 4/22/09, 5/7/09.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 28, 29 and 36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28, 29 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/22/09 has been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28, 29, and 36 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,527,938 to Bates et al. in view of US 6,099,562 to Ding et al.

### ***Response to Arguments***

Applicants' arguments have been fully considered, but are not persuasive. Applicants argue that the claims now require that the biobeneficial polymer be conjugated to the styrene containing polymer by a process comprising acylation of styrene monomers. Applicants point out that the prior art uses processes other than acylation to attach PEG to the topcoat of the stent. In response, the limitation at issue here is a product by process limitation. Such limitations are only afforded weight to the

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extent that the process imparts a patentable distinction on the product. Applicants have not alleged that there are any differences in the product formed by the methods of the prior art, and a product formed by the claimed method. The Examiner has analyzed the prior art and the method in the claims, and has also concluded that the two methods do not yield different materials. For that reason, the rejection must be maintained.

It is clear from the specification that conjugating a biobeneficial polymer to a styrene monomer by a process comprising acylation does not mean that the final product will have acyl groups, or derivatives of acyl groups. Figures 1 and 2 both show processes wherein a biobeneficial polymer is conjugated to a styrene monomer in a process comprising acylation, and the resulting conjugate does not contain any acyl groups. On the contrary, the styrene is bound to the PEG by way of an amine group in those figures. Figures 1 and 2, of course, do not limit the claimed invention or the nature of products that might result from the claimed product by process – the claims cover products with more varied linkages than those shown in the Figures. Figures 1 and 2 are therefore strong evidence that the acyl group can be converted into a new moiety bearing no resemblance to its original form during the “process comprising acylation of the styrene monomers.” It is reasonable to conclude that the claimed process step does not necessarily result in a product where an acyl group, or any other particular functional group, is present. Turning to the prior art, Ding teaches that PEG can be bound to the polymer topcoat by a process involving forming amines (or similar nitrogen reactive groups) on the polymer topcoat, and then reacting “electrophilically activated PEG” therewith. Col. 5-6, and example 2. The electrophilically activated PEG

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includes PEG tresylate, glycidyl ester, etc. Example 2. A chemist understands that the result of this manipulation is PEG bound to the topcoat by way of a nitrogen containing group, such as an amine, amide, urethane, or similar.

By comparison with the specification and particularly the Examples, it is reasonable to conclude that the type of linkages formed by the prior art could also be formed by a process comprising acylating styrene monomers. Notably, the inventive examples in the specification include PEG that is conjugated by way of a nitrogen containing moiety, just as the prior art conjugates PEG by way of a nitrogen containing moiety. Because the evidence does not indicate that the process imbues any features on the claimed product that render the product non-obvious, the added process limitations do not overcome the prior art rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/  
Examiner, Art Unit 1618